UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **THE WAVE ONE CASES IDENTIFIED IN EXHIBIT A TO DEFENDANT'S RESPONSE**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN REPLY TO DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF MS. ELAINE DUNCAN

Ethicon's brief in Opposition to Plaintiffs' Motion to Exclude the Opinions and Testimony of Elaine Duncan is nothing more than an attempt to backdoor inadmissible evidence concerning the FDA into this litigation through Ms. Duncan.

Moreover, Ethicon's argument that if Plaintiffs' experts Anne Wilson and Dr. Russell Dunn can testify, it should "in fairness…be allowed to call Ms. Duncan to set the record straight" (Def's. Br. at 1) centers around the premise that Ms. Duncan addresses many of the same subject matters as Plaintiffs' experts. However, this misses the most important point, namely that Ms. Duncan and Plaintiffs' experts utilized separate methodologies for their opinions.[1] Here, Ms. Duncan's testimony, unlike that of Ms. Wilson and Dr. Dunn, relies on inadmissible evidence concerning the FDA—evidence that Ms. Duncan herself equates to federal-government endorsement of Ethicon's mesh devices. *See* Ex. A, Duncan TVT-R Report at 12 ("…the evidence of safety and performance for a surgical mesh, follows the FDA's standard…" and

[1] This Court has long recognized that *Daubert* does not permit this type of simplistic approach. This Court has always looked at each expert witness individually, assessing his or her qualifications and methodologies separately in reaching a conclusion.

"Ethicon's TVT 510(k) applications followed this guidance."). Ms. Duncan's testimony also relies on clinical information in the AUGS statement, while Ms. Wilson's and Dr. Dunn's does not. As the Court knows, Ms. Duncan is not a physician and simply parroting the AUGS statement (with no background to do so) and saying the device is fine because she thinks the FDA said so is really just impermissible advocacy wrapped up in an expert. Thus, when Ms. Duncan's methodologies are actually examined, it is clear that Defendant's attempts to defend her fall short. Ethicon's attempt to insert the FDA regulations into this litigation by using Ms. Duncan must be denied.[2]

ARGUMENT

I. Ms. Duncan's opinions must be excluded because they rely on the FDA 510(k) and regulatory processes

Ethicon concedes that Ms. Duncan relies on the FDA regulations in support of her opinions, arguing instead that: (1) reliance on regulations outside the 510(k) process is permissible; (2) Ms. Duncan's opinions can survive even if all FDA regulations are excluded; and (3) Ethicon's compliance with the FDA 510(k) process should be admitted. None of these positions is correct.

A. This Court has routinely excluded all referenced to the FDA from evidence, and not just reference to the 510(k) process

This Court has routinely excluded all reference to the FDA from evidence, and not just reference to the 510(k) process. *See Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 756 (S.D. W. Va. 2014) ("In sum, the parties may not present evidence regarding the 510(k) clearance process or subsequent FDA enforcement actions. This is consistent with prior rulings by this court."). This Court has also routinely excluded under *Daubert* experts whose opinions

[2] While Ethicon attempts to recast Plaintiffs' motion as a limited one attacking specific opinions only, *see* Def's. Br. at 15-17, the reality is that the Plaintiffs challenge all of Ms. Wilson's opinions. All of the opinions rest on inadmissible FDA evidence.

rely on or concern the FDA's regulatory activities. *See Winebarger v. Boston Sci. Corp*. No. 2:13-cv-28892 2015 U.S. Dist. LEXIS 53892, at *54-55 ("If I allowed BSC to express to the jury that its product complied with FDA regulations, the jury would then view the product with the gloss of federal-government endorsement."); *see also Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762 2014 U.S. Dist. LEXIS137189, at *95-96 (S.D. W. Va. Sept 29, 2014) ("Given that the probative value of expert testimony on FDA requirements is substantially outweighed by the risk of jury confusion, I cannot admit Dr. Pence's testimony as it relates to the FDCA or FDA regulations."). Ethicon's argument that that the FDA regulations at the core of Ms. Duncan's opinions are *relevant* simply ignores the prior rulings of this Court. *See* Def's Br. at 6-7. Rather, the proper inquiry here is whether any amount of relevance that Ms. Duncan's FDA regulations have is *substantially outweighed by the danger of misleading the jury*. Here, if Ms. Duncan were allowed to express to the jury that Ethicon's products complied with FDA regulations, the jury would then view the product "with the gloss of federal government endorsement." *See Winebarger* 2015 U.S. Dist. LEXIS 53892, at *54-55. Ethicon has offered no reason why this should be any different and certainly not for this expert. For this reason, Ethicon's attempt to insert the FDA regulations into this litigation by using Ms. Duncan must be denied.

B. Ms. Duncan's opinions are premised on Ethicon's compliance with the 510(k) process and FDA regulations, and her opinions cannot survive if those FDA regulations are excluded

Ethicon backpedals, and now claims that Ms. Duncan may be able to offer her opinions without reference to the 510(k) process, but that is a misrepresentation of the record in this case. Def's. Br. at 7-8. Ms. Duncan's opinions in this case repeatedly express that Ethicon's products complied with FDA regulations: "In the US, the performance of the product is evaluated by way of examination of the application [510(k)] through the appropriate and knowledgeable branch of

the FDA. The application contents, and thus ***the evidence of safety and performance for a surgical mesh***, follows the FDA's standard." Ex. A, Duncan TVT-R Report at 12 (emphasis added). Ms. Duncan also expressed that "I have researched the FDA's records and confirmed that ***Ethicon received a number of 510(k) clearances for the TVT products***. These applications follow strict submission content examinations and must ***meet the FDA's professional, scientific review standards***. Ex. A, Duncan TVT-R Report at 12 (emphasis added); *see also* Ex. B, Duncan Dep. October 6, 2015 at 177:19-178:3 ("Q. One of the things that you rely on to reach that conclusion concerning due diligence is the fact that Ethicon received a number of 510(k) clearances for the TVT products? A. The family of products. That was one of the things I looked at. Q. And that's what I asked you. So the answer is yes? A. Yes."). Ms. Duncan expressly opined that "it's my conclusion that this device, based on the clinical experience and ***the robust endorsement of this device*** by the AUGS organization and ***even the FDA***, that I would be fool hardy to try to suggest that there's a better way to make this product." Ex. B, Duncan Dep. October 6, 2015 at 23:8-12.[3] These are precisely the type of opinions that this Court has previously excluded and therefore Ms. Duncan's testimony must also be excluded.

Ethicon's attempt to fix the problem they created by suggesting that Ms. Duncan simply be allowed to testify without reference to the FDA is unavailing. Ms. Duncan herself admitted at her prior deposition in the *Mullins* case that if she did a report without the FDA evidence, the result would be "peculiar at best" and "wouldn't be what I normally do as a part of due diligence." Ex. B, Duncan Dep. October 6, 2015 at 167:15-168:12; *see also id.* at 185:7-10 ("Q. Are you saying that you could not do a comprehensive due diligence without considering the FDA regulations in connection with this report? A. It would be less than professional.").

[3] Moreover, Ms. Duncan also now takes the position that she has taken into account "any regulatory approval in any country" in arriving at her opinions in this case. Ex. D, Duncan Dep. March 31, 2016 at 118:13-22.

Accordingly, even Ms. Duncan admitted that offering an opinion in this manner would not meet the standards set forth under Daubert for a reliable methodology. In contrast, Plaintiffs' expert, Anne Wilson has testified that FDA regulations are not necessary to her analysis and opinions. *See* Ex. C, Wilson Dep. September 17, 2015 at 393:22-394:22. Ethicon's attempt to equate the methodologies of Ms. Duncan and Ms. Wilson fall short in this regard and Ethicon's attempt to push the FDA regulations into this litigation must be denied.

C. This Court has excluded evidence regarding the 510(k) clearance process of the product at issue in every previous case in these MDLs

In every previous case in these MDLs, this Court has excluded evidence regarding the 510(k) clearance process of the product at issue. *E.g., Bellew v. Ethicon, Inc.* No.2:13-cv-22473 2014 LEXIS 165709, at *28-29 (S.D. W. Va. Nov. 25, 2014) ("evidence as to the FDA's 510(k) process and lack of enforcement action should be excluded under *Federal Rule of Evidence 403* because of the danger of misleading the jury, confusing the issues, and unfair prejudice…and if such testimony comes in via expert testimony, the expert would be effectively offering a legal conclusion."). This Court's position on this issue was recently upheld by the Fourth Circuit. *Cisson v. C.R. Bard, Inc.* 810 F.3d 913, 919-923 (4th Cir. 2016). Here, Ethicon has not provided any reason to depart from this position. Def's Br. at 9. Ethicon's unsupported argument against this Court's established position falls short, and Ethicon's attempt to use Ms. Duncan as a means to insert the FDA and 510(k) process into these cases must be denied.

II. Ms. Duncan's methodology is unreliable and distinct from that of Ms. Wilson

There is a clear distinction between the industry standards that Ms. Wilson discusses (*i.e.*, ISO standards) and the FDA regulations that Ms. Duncan relies upon and discusses—and this Court's prior rulings recognize that distinction. In *Cisson*, this Court allowed the defendant to present evidence regarding its compliance with ISO standards. *Cisson v. C.R. Bard, Inc.*, No.

2:11-cv-00195 2013 U.S. Dist. LEXIS 149976, at *36 (S.D. W.V. Oct. 18, 2013) ("Similarly, evidence that Bard complied with standards set by the International Standards Organization (ISO) would not preclude the jury from awarding punitive damages. This evidence shows that Bard conducted biocompatibility and risk analysis in accordance with ISO standards."). In contrast, the FDA regulations relied upon by Ms. Duncan would cause the jury to "view the product with the gloss of federal government endorsement." *Winebarger* 2015 U.S. Dist. LEXIS 53892, at *54-55. Ms. Wilson's ISO standards do not carry the same prejudicial force—the government does not promulgate them and jurors are not familiar with them.

III. Ethicon's attempts to rewrite Ms. Duncan's AUGS related testimony should be denied

Ethicon attempts to explain away Ms. Duncan's reliance on the AUGS position statement, claiming that Ms. Duncan "does not opine that the AUGS position statement is substantively correct" and that the "AUGS position statement plays only a minor role in her analysis." Def's. Br. at 12-13. If Ms. Duncan lacks knowledge of the substantive correctness of the AUGS statement, she should not be permitted to opine that the "proof is in the pudding, that when we look at a device, which is functioning as intended and safe, I would not recommend to a company to go back and redesign it." Ex. B, Duncan Dep. October 6, 2015 at 25:6-9. Ms. Duncan offered the AUGS statement as support for the opinion that Ethicon's devices were functioning as intended and safe in a clinical setting; if she lacks knowledge of its substantive correctness, she lacks a reliable foundation for her opinions.

CONCLUSION

For each of the foregoing reasons, along with those in the original brief, Plaintiffs request that the testimony of Ms. Duncan be excluded in its entirety.

Dated: May 16, 2016 By: /s/ Edward A. Wallace

Edward A. Wallace
Mark R. Miller
Michael H. Bowman
Wexler Wallace
55 W. Monroe St. Ste. 3300
Chicago, IL 60603
Phone: (312) 346-2222
eaw@wexlerwallace.com
mrm@wexlerwallace.com
mhb@wexlerwallace.com

Bryan F. Aylstock, Esq.
Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563
(850) 202-1010
(850) 916-7449 (fax)
rbaggett@awkolaw.com
baylstock@awkolaw.com

Thomas P. Cartmell, Esq.
Jeffrey M. Kuntz, Esq.
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1102
Fax 816-531-2372
tcartmell@wcllp.com
jkuntz@wcllp.com

CERTIFICATE OF SERVICE

I hereby certify that on May 16, 2016 I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive services in this MDL.

By: /s/ Edward A. Wallace